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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/526,329 03/15/00 CROCE

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EXAMINER

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ART UNIT	PAPER NUMBER
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1642  
DATE MAILED:*4*

04/02/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. 09/526,329	Applicant(s) Croce et al
Examiner Anne Holleran	Group Art Unit 1642



Responsive to communication(s) filed on \_\_\_\_\_

This action is FINAL.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-93 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-93 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

**DETAILED ACTION**

Prior to setting forth the restriction requirement, Applicant's attention is drawn to the numbering of the claims. A claim numbered 24 was omitted. Accordingly, claims 25-94 have been renumbered as claims 24-93, respectively, under 37 C.F.R. 1.126. The groups have been set out using the renumbered claims.

*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-5, 8-16, 22-25 and 29, drawn to nucleotides encoding a Tc1-1b protein, vectors, host cells, antisense constructs, diagnostic kit, classified in class 536, subclass 23.5.
  - II. Claims 6, 7, 17 and 19, drawn to proteins and fusion proteins, classified in class 530, subclass 350.
  - III. Claim 18, drawn to antibodies, classified in class 530, subclass 387.1.
  - IV. Claims 20-21, 26 and 27, drawn to methods of detecting a target sequence, classified in class 435, subclass 6.
  - V. Claim 28, drawn to methods of detecting a protein, classified in class 435, subclass 7.1.
  - VI. Claim 30 and 31, drawn to methods of treating a disease state, classified in class 514, subclass 44.

- VII. Claims 32-36, 39-47, 53-56 and 60, drawn to nucleotides encoding a Tng 1 protein, vectors, host cells, antisense constructs, diagnostic kit, classified in class 536, subclass 23.5.
- VIII. Claims 37, 38, 48 and 50, drawn to proteins and fusion proteins, classified in class 530, subclass 350.
- IX. Claim 49, drawn to antibodies, classified in class 530, subclass 387.1.
- X. Claims 51, 52, 57 and 58, drawn to methods for detecting a target sequence, classified in class 435, subclass 6.
- XI. Claim 59, drawn to methods for detecting a Tng 1 protein, classified in class 435, subclass 7.1.
- XII. Claims 61 and 62, drawn to methods for treating a disease state, classified in class 514, subclass 44.
- XIII. Claims 63-67, 70-78, 84-87 and 91, drawn to nucleotides encoding a Tng2 protein, vectors, host cells, antisense constructs, diagnostic kit, classified in class 536, subclass 23.5.
- XIV. Claims 68, 69, 79 and 81, drawn to proteins and fusion proteins, classified in class 530, subclass 350.
- XV. Claim 80, drawn to antibodies, classified in class 530, subclass 387.1.
- XVI. Claims 82, 83, 88 and 89, drawn to methods for detecting a target sequence, classified in class 435, subclass 6.

XVII. Claim 90, drawn to methods for detecting a Tng 2 protein, classified in class 435, subclass 7.1.

XVIII. Claims 92 and 93, drawn to methods for treating a disease state, classified in class 514, subclass 44.

2. The inventions are distinct, each from the other, for the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute apparently distinct inventions for the following reasons: the polynucleotides of either of groups I, VII or XIII, the polypeptides of group II, VIII or XIV and the antibodies of group III, IX or XV are chemically distinct products unrelated in sequence and separately classified, having separate fields of search. Other than the fact that polypeptides and polynucleotides are derived from the same cell type, the polynucleotides of either of groups I, VII or XIII and the polypeptides of either of groups II, VIII or XIV have no relationship to each other structurally and no chemical structural relationship to the antibodies of either of groups III, IX or XV. The products of either of groups I, VII or XIII and either of groups II, VIII or XIV can be independently synthesized by chemical means. An antibody is encoded by an entirely different DNA than that of the protein which is bound by that antibody, and the primary sequence of the antibody bears no relationship to the sequence of the detected protein. Each of the products has separate and unrelated uses and are not disclosed as being capable of use together. Further, it would place undue burden on the examiner to examine several independent inventions in one application. It is also noted that groups I, VII and XIII, drawn to

nucleic acid products are separate and distinct inventions because the nucleic acids of each of these groups encodes a separate and distinct protein product. Additionally, groups II, VIII and XIV, and groups III, IX and XV are separate and distinct inventions because the proteins and antibodies of each of these groups are separate and distinct protein and antibody products.

Each of inventions IV, V, VI, X, XI, XII, XVI, XVII and XVIII is directed to a separate and distinct process. Each of the processes are distinct both physically and functionally, require different steps and make or use different products. The methods of nucleic acid detection of groups IV, X and XVI are separate and distinct inventions from the methods of protein detection of groups V, XI and XVIII because each of the methods uses different steps and different products and is different functionally. Either of these groups of methods is a separate and distinct invention from the methods of treatment of groups VI, XII and XVIII because methods of detection are different functionally and have different endpoints from methods of treatment. Each of groups IV, X and XVI is a separate and distinct invention because each of the groups of methods is drawn to methods of detecting separate and distinct nucleic acid molecules. Each of groups V, XI and XVII is a separate and distinct invention because each of the groups of methods is drawn to methods of detecting separate and distinct protein products. Each of groups VI, XII and XVIII is a separate and distinct invention because each of the groups of methods is drawn to methods of treatment using separate and distinct nucleic acid molecules.

Inventions I, VII or XIII and IV, X, XVI, VI, XII or XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the inventions of I, VII or XIII can be used in methods of making a recombinant protein, methods of detection of a nucleic acid or in methods of treatment by antisense technology which are all methods which are materially different from each other.

Inventions III, IX, or XV and V, XI or XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of III, IX or XV can be used in methods of treatment which are materially different methods than are the methods of protein detection of groups V, XI or XVII.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter and because searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

4. Applicants have presented method claims in improper Markush format (see **Ex parte Markush**, 1925 C.D. 126 and **In re Weber**, 198 USPQ 334) and this application contains claims drawn to a misjoined Markush group that contains multiple, independent and distinct inventions.

Groups VI, XII and XVIII are drawn to separate and distinct methods because the methods use separate and distinct products.

Upon election of either group VI, XII or XVIII, Applicant is additionally required to elect a single species of method of treatment, either a method drawn to treatment using nucleic acids (antisense) or a method of treatment using antibodies. This requirement is not to be construed as a requirement for an election of species, since each of the products recited in alternative form is not a member of a single genus of product. Thus, each of the claimed methods constitutes an independent and patentably distinct invention.

Upon election, applicants are **required** to amend the claims to set forth the elected inventive groups, otherwise these claims will be rejected as being in improper Markush format.

5. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

*ALH*  
Anne L. Holleran  
Patent Examiner  
March 30, 2001

*G. Bansal*  
GEETHA P. BANSAL  
PRIMARY EXAMINER